In the Claims:

1. (Currently Amended) A process for preparing an inhalable powder, wherein N+m substantially equal portions of an excipient having a larger average particle size ~~distribution~~ and N equal portions of an active substance having a smaller average particle size ~~distribution~~ are added in alternate layers into a suitable mixing vessel and after all the excipient and active substance have been added the 2N+m layers of the two components are mixed together using a suitable mixer, wherein a portion of the excipient having the larger particle size is added first, and wherein N is an integer >5 and m denotes 0 or 1.

2. (Cancelled)

3. (Original) A process according to claim 1, characterised in that the individual portions of excipient and active substance are added in layers through a suitable screening apparatus.

4. (Original) A process according to claim 1, characterised in that m denotes 1.

5. (Original) A process according to claim 1, characterised in that the inhalable powder obtained contains less than 5% of active substance.

6. (Original) A process according to claim 5, characterised in that the inhalable powder obtained contains less than 2% of active substance.

7. (Original) A process according to claim 1, characterised in that the active substance has a particle size of from 0.5 to 10 μm.

8. (Original) A process according to claim 7, characterised in that the active substance has a particle size of from 1 to 6 μm.

9. (Original) A process according to claim 1, characterised in that the excipient has a mean particle size of from 10 to 100 μm.

10. (Original) A process according to claim 9, characterised in that the excipient has a mean particle size of from 15 to 80 μm.

11. (Original) A process according to claim 1, wherein the excipient is a single excipient or a mixture of different excipients.

12. (Original) A process according to claim 1, characterised in that the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80 μm and finer excipient with an average particle size of 1 to 9 μm, the proportion of finer excipient constituting 1 to 20% of the total amount of excipient.

13. (Original) A process according to claim 1, wherein the active substance is a single active substance or two or more different active substances.

14. (Original) A process according to claim 1, characterised in that the active substance consists of one or more compounds selected from among the betamimetics, anticholinergics, corticosteroids and dopamine agonists.

15. (Original) An inhalable powder obtained by the process according to claim 1.

16. (New) The process according to claim 1 wherein the active substance is selected from the group consisting of betamimetics, anticholinergics, corticosteroids, dopamine agonists, and pharmaceutically acceptable salts, solvates or hydrates thereof, and mixtures thereof.

17. (New) The process according to claim 16 wherein the active substance comprises an anticholinergic compound or its pharmaceutically acceptable solvate, hydrate or salt.

18. (New) The process according to claim 17 wherein the anticholinergic compound comprises tiotropium.

19. (New) The process according to claim 17 wherein the pharmaceutically acceptable salt of the anticholinergic compound comprises tiotropium bromide.

20. (New) The process according to claim 17 wherein the pharmaceutically acceptable solvate or hydrate of the anticholinergic compound comprises tiotropium bromide monohydrate.

21. (New) The process according to claim 1 wherein the excipient is selected from the group consisting of monosaccharides, disaccharides, oligosaccharides, polysaccharides, polyalcohols, salts, and mixtures thereof, each optionally in its hydrate forms.

22. (New) The process according to claim 21 wherein the excipient comprises a monosaccharide or a disaccharide, or a combination thereof.

23. (New) The process according to claim 21 wherein the excipient comprises glucose or lactose or a combination thereof, each optionally in its hydrate form.

24. (New) The process according to claim 22 wherein the excipient comprises a disaccharide.

25. (New) The process according to claim 23 wherein the excipient comprises lactose or lactose monohydrate.

26. (New) The inhalable powder according to claim 15 wherein the active substance is selected from the group consisting of betamimetics, anticholinergics, corticosteroids, dopamine agonists, and pharmaceutically acceptable salts, solvates or hydrates thereof, and mixtures thereof.

27. (New) The inhalable powder according to claim 26 wherein the active substance comprises an anticholinergic compound or its pharmaceutically acceptable solvate, hydrate or salt.

28. (New) The inhalable powder according to claim 27 wherein the anticholinergic compound comprises tiotropium.

29. (New) The inhalable powder according to claim 27 wherein the pharmaceutically acceptable salt of the anticholinergic compound comprises tiotropium bromide.

30. (New) The inhalable powder according to claim 27 wherein the pharmaceutically acceptable solvate or hydrate of the anticholinergic compound comprises tiotropium bromide monohydrate.

31. (New) The inhalable powder according to claim 1 wherein the excipient is selected from the group consisting of monosaccharides, disaccharides, oligosaccharides, polysaccharides, polyalcohols, salts, and mixtures thereof, each optionally in its hydrate form.

32. (New) The inhalable powder according to claim 31 wherein the excipient comprises a monosaccharide or a disaccharide or a combination thereof.

33. (New) The inhalable powder according to claim 32 wherein the excipient comprises glucose or lactose or combinations thereof, each optionally in its hydrate form.

34. (New) The inhalable powder according to claim 32 wherein the excipient comprises a disaccharide.

35. (New) The inhalable powder according to claim 33 wherein the excipient comprises lactose or lactose monohydrate.

STATEMENT OF STATUS AND SUPPORT FOR ALL CHANGES TO THE CLAIMS

PURSUANT TO 37 CFR 1.173(c)

Claims 1 and 3-35 are pending. Of these, claims 1 and 3-15 are from the patent. Claim 1 has been amended. Claim 2 has been canceled. Claims 3-15 are unchanged. Claims 16-35 have been added.

Claim 1 has been amended by changing the term "particle size distribution" to read --average particle size--. Support for the amendment may be found, e. g., in col. 1, lines 33-37 (a statement of the problem); col. 2, lines 27 and 33 ("smaller particle size" and "larger particle size", respectively); and col. 2, lines 45-53 ("the smaller particles (active substance) have an average particle size of 0.5-10 μm...the excipient (larger particles) have an average particle size of 10 to 100 μm..."). See also column 3, lines 13-33 describing the invention in terms of "average particle size".

Claim 2 has been canceled (or actually was previously canceled by applicants in the amendment filed on March 14, 2003, and is made of record herein.)

New claims 16-35 have been added, and all are directly or indirectly dependent on claim 1. The new claims, all dependent claims, are presented to provide full support for the chemical character of the invention as originally conceived. Support for the new claims may be found through the patent, e. g.,

Claim 16 – col. 4, lines 13-16
Claim 17 – col. 4, lines 55-58
Claim 18 – col. 5, lines 9-14
Claim 19 – col. 5, lines 24-26
Claim 20 – col. 5, lines 30-33
Claim 21 – col. 6, lines 28-35
Claim 22 – col. 6, lines 35-36
Claim 23 – col. 6, line 36

Claim 24 – col. 6, line 36

Claim 25 – col. 6, lines 39-40

Claims 26-35 correspond to claims 16-25 and recite all of the limitations referred to in claims 16-25, with the additional element being the inhalable powder of claim 15 (col. 6, lines 41-44).